

REMARKS

Claims 236 and 238-306 are currently pending. Claim 237 has been cancelled herein. Claims 242, 259 and 275-306 have been previously withdrawn. Claims 236, 238-241, 243-258 and 260-274 are now under examination. Minor amendments have been made to the claims to overcome the rejections of the claims under 35 U.S.C. § 112. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

REJECTION UNDER 35 U.S.C. § 112

Claims 236-241, 243-258 and 260-274 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner has asserted in the present Office Action that the "specification, while being enabling for a method of producing a heterologous polypeptide in plant comprising a) providing a transgenic plant comprising a DNA molecule containing a promoter operably linked to a DNA sequence containing a sequence complementary to a coding sequence for a heterologous polypeptide, a sequence complementary to an IRES from a plant virus and a 3' UTR of a first positive strand single-stranded RNA virus ... closely related to the first one, does not reasonably provide enablement for a method for producing heterologous polypeptide in any cell or any IRES from any source or any stimulus for synthesis of an RNA complementary to an RNA transcript of the recombinant DNA." This rejection is respectfully traversed.

Applicant gratefully acknowledges the Examiner's careful consideration of Applicant's arguments and finding of enabled subject matter in the specification. Nevertheless, Applicant respectfully submits that the specification as originally filed is

enabling of the full scope of the Applicant's claims for two main reasons, provided in the Applicant's response filed on August 29, 2008 and reiterated here. First, evidence has been provided by the Applicant to show that animal viral IRES elements work in plant cells and that one of ordinary skill in the art can, without undue experimentation, construct a DNA molecule comprising a compatible complementary IRES sequence derived from either plant, animal or viral sources for expression and use in transgenic plants and transgenic animal cells.

Second, at the time of filing the present application, one of ordinary skill in the art possessed a high level of skill, *i.e.*, a Ph.D. molecular biologist or plant biologist. The person of ordinary skill in the art would have had within their possession routine assays to determine whether a particular IRES sequence(s) could be inserted into the recombinant DNA construct of the present embodiments. Therefore, one of ordinary skill in the art could make and use the claimed inventions without undue experimentation.

In order to advance prosecution, and without acquiescing to the Action's assertions of lack of enablement of the presently rejected claims, the Applicant has amended the claims to recite methods for producing heterologous polypeptides in transgenic plants and transgenic plant cells. As noted by the Examiner, enablement is provided in the specification with respect to plant virus IRES elements. Therefore, the claims as amended herein recite plant virus IRES sites. In addition, the Applicant has amended the claims to recite activation and stimulus of the transgenic plants and transgenic plant cells by infecting with second positive strand single-stranded RNA plant virus.

Support for the present amendments “transgenic plant cell” can be found in the specification (International Application PCT/US2004/021451) at paragraph [0020]. Support for “3' UTR of a first positive strand single-stranded RNA plant virus” can be found at paragraph [0017]. Support for “second positive strand single-stranded RNA plant virus” can be found at paragraph [0030].

Accordingly, Applicant respectfully requests that the present rejection of Claims 236-241, 243-257 and 260-274 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

CONCLUSION

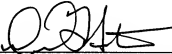
Applicant submits that the claimed methods for producing a heterologous polypeptide are not unduly broad – they are focused on DNA constructs that are used to transfect and express the polypeptides in transgenic plants and transgenic plant cells. In particular, the claims have been amended to recite the enabled subject matter noted by the Examiner in the present Office Action in order to advance prosecution of this case. Practice of these methods does not require undue experimentation, beyond the level of IRES functionality in specific plant cells using the methods taught in the specification and standard experiments routine in the art. The study of IRES mode of translation in plants and plant cells in particular, were well understood to have utility, and design of such IRES/host cell compatibility analyses were well within the skill of the ordinary artisan at the time of filing. Accordingly, Applicant submits that the amended claims are fully enabled, and request withdrawal of the rejections under 35 U.S.C. §112.

It is believed that the amended claims are now in condition for allowance and the Applicant earnestly requests passing the present application to allowance. Applicant reserves the right to file continuation applications covering the subject matter covering the non-elected inventions and methods and DNA molecules incorporating animal, insect and yeast viral IRES elements and production of heterologous polypeptides in cells other than in plants.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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